CLAIMS

1. A method for the *in vitro* diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate, characterized in that it comprises the step consisting of detection, in a biological sample from a patient suspected of suffering from a benign pathology of the prostate or from an adenocarcinoma of the prostate, of the activatable free form of PSA.

2. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in claim 1, characterized in that it comprises the steps consisting in:

i) bringing a binding partner capable of binding specifically to activatable free PSA into contact with a biological sample from a patient suspected of suffering from a benign pathology of the prostate or of an adenocarcinoma of the prostate,

ii) demonstrating the capture of the activatable free form of PSA by said binding partner,

iii) calculating the ratio of the amount of activatable free form of PSA detected in step ii) to the amount of a form of PSA other than the activatable free form, present in a sample of the same nature taken from the same individual, and

iv) determining whether the patients are suffering from an adenocarcinoma of the prostate or from a benign pathology of the prostate by comparing the value of the ratio determined in step iii) with a predetermined threshold value, chosen according to the type of ratio used and representative of the detection limit of each pathology.

3. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in claim 2, characterized in that said binding partner used in step i) is capable of recognizing the epitope mimicked by the sequence SEQ ID No. 1

4. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in either of claims 2 or 3, characterized in that

said binding partner used in step i) is an antibody or an antibody fragment.

5. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in any one of claims 2 to 4, characterized in that the demonstration of the capture of the activatable free form of PSA by said binding partner is carried out by indirect detection by means of a detection partner, preferably using an anti-total PSA antibody.

6. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in one of claims 2 to 4, characterized in that the demonstration of the capture of the activatable free form of PSA by said binding partner is carried out by determining the enzymatic activity of the immunopurified and activated, activatable free form of PSA.

7. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in any one of claims 2 to 6, characterized in that it uses, in addition to the binding partner capable of binding specifically to activatable free PSA, an antibody capable of increasing the enzymatic activity of PSA.

8. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in any one of claims 2 to 7, characterized in that the form of PSA other than the activatable free form used for calculating the ratio is the inactive free form of PSA or the cleaved and denatured free forms of PSA.

9. A diagnostic kit for diagnosing an adenocarcinoma of the prostate or a benign pathology of the prostate, characterized in that it comprises:
- a binding partner capable of binding specifically to activatable free PSA, and
- means for assaying the forms of PSA other than the activatable free form.

10. The diagnostic kit as claimed in claim 9, characterized in that said binding partner is capable of recognizing the epitope mimicked by the sequence SEQ ID No. 1,

preferably an antibody or an antibody fragment.

11. The diagnostic kit as claimed in either of claims 9 and 10, characterized in that said means are antibodies or antibody fragments.

12. A conjugate consisting of a binding partner capable of binding specifically to activatable free PSA and of the activatable free form of PSA.

13. The conjugate as claimed in claim 12, characterized in that said binding partner is capable of recognizing the epitope mimicked by the sequence SEQ ID No. 1.

14. The conjugate as claimed in either of claims 12 and 13, characterized in that the activatable free form of PSA is activated.

15. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in claim 1, characterized in that it comprises the steps consisting in:

i) bringing a binding partner capable of binding to activatable free PSA in a nonspecific manner into contact with a biological sample from a patient suspected of suffering from a benign pathology of the prostate or from an adenocarcinoma of the prostate,

ii) demonstrating the capture of the activatable free form of PSA by said binding partner by determining the enzymatic activity of the activatable free form of PSA, after activation of the activatable free form of PSA,

iii) calculating the ratio of the amount of activatable free form of PSA detected in step ii) to the amount of a form of PSA other than the activatable free form, present in a sample of the same nature taken from the same individual, and

iv) determining whether the patients are suffering from an adenocarcinoma of the prostate or from a benign pathology of the prostate by comparing the value of the ratio determined in step iii) to a predetermined threshold value, chosen according to the type of ratio used and representative of the detection limit of each pathology.

16. The method for the diagnosis of a benign pathology of the prostate or of an adenocarcinoma of the prostate as claimed in claim 15, characterized in that the activation of the activatable free form of PSA is carried out using an antibody capable of increasing the enzymatic activity of PSA.